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EXAMINER
LAMM, MARINA

ART UNIT	PAPER NUMBER
1616	21

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/661,693	Applicant(s) PATHER ET AL.	
	Examiner Marina Lamm	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,23,25-36 and 83-104* is/are pending in the application.

4a) Of the above claim(s) *98-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,23,25-36 and 83-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment is made of the amendment filed 5/29/03. Claims pending are 22, 23, 25-36 and 83-104. Claim 24 has been cancelled. Claims 88-104 are new.

Election/Restrictions

1. Newly submitted claims 98-104 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Originally claimed invention and that claimed in new Claims 98-104 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the originally claimed tablet does not require the oral mucosa penetration enhancer of Claim 98. The subcombination has separate utility such as a tablet.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 98-104 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

2. Applicant is advised that should claim 91 be found allowable, claim 92 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 95 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-4 of copending Application No. 10/080,016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention overlaps with that previously claimed. Thus, Claim 95 of the instant application is directed to a tablet for oral administration across the oral mucosa comprising a pharmaceutically effective amount of fentanyl or its salt, at least one pH adjusting substance and at least one saliva activated effervescent couple present in an amount which is greater than the amount necessary for tablet disintegration and which is sufficient to increase absorption of the medicament across the oral mucosa, and wherein said amount is between about 5 and about 80% by weight. Claim 2 of the copending application is directed to a pharmaceutical dosage form for oral administration across the oral mucosa comprising a pharmaceutically effective amount of fentanyl or its salt, at least one saliva activated

effervescent agent present in an amount sufficient to increase absorption of the medicament across the oral mucosa and at least one pH adjusting substance. Claim 3 of the copending application depends from Claim 2 and recites that the pH adjusting substance is a base. Claim 4 depends from Claim 3 and recites specific pH adjusting substances. The difference between Claim 95 of the instant invention and Claim 2 of the copending application is that Claim 2 does not require the amount of an effervescent agent be greater than the amount necessary for tablet disintegration. However, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to employ an effervescent agent in the amount greater than the amount necessary for the disintegration of the pharmaceutical formulation to insure complete disintegration of the formulation. Further, the instant Claim 95 does not recite specific pH adjusting agents. However, the compounds of Claim 4 are recited in Claims 85 and 86 of the instant invention and they are well known and widely used in the pharmaceutical art for adjusting pH. The selection of a known material based on its suitability for its intended use is obvious absent showing of unexpected results. Thus, the invention claimed in Claim 95 overlaps with that claimed in Claims 2-4 of the copending application 10/080,016.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

4. Applicant's arguments, see pp. 10-14 of the response, filed 5/29/03, with respect to the rejection of Claims 22 and 84 under 35 U.S.C. 112, first paragraph, have been fully considered and are persuasive. The rejection of Claims 22 and 84 under 35 U.S.C. 112, first paragraph has been withdrawn.

5. Applicant's arguments, see pp. 14-19 of the response, filed 5/29/03, with respect to the rejection(s)of claim(s) 22-24, 26-36 and 83-87 under 35 U.S.C. 102(b) and claims 22, 25 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference. See below.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 22, 23, 25-36, 83-94 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (US 6,071,539).

8. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter

of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Robinson et al. teach oral formulations, such as tablets, containing effervescent granules, an effective amount of a therapeutic compound such as an analgesic, antipsychotic (e.g. prochlorperazine), antidiabetic (e.g. insulin) or a pharmaceutically acceptable salt thereof, lubricants, flavors, fillers, colors, non-effervescent disintegrants and other conventional additives. See col. 3, lines 1-9; col. 7, lines 24-59; col. 8, lines 35-67; col. 9, lines 30-67; col. 10-11. The effervescent granules of Robinson et al. contain an effervescent couple (i.e. an acidic agent such as citric acid, tartaric acid, fumaric acid and an alkaline agent such as sodium carbonate, sodium dihydrogen phosphate, potassium carbonate) and a binder. See Abstract; Examples. By controlling the relative ratio of acidic agent: alkaline agent, the effervescent granules can be used to regulate the pH of their environment (e.g. mouth). See col. 4, lines 53-55. The ratio of the acidic agent and alkaline agent can be determined according to the pH required for dissolving an active ingredient included in a formulation as follows: "When the solubility of the active ingredient increases at the acid side, the pH of the solution is lowered by adding the acidic agent in an amount more than equivalent to the alkaline agent. When the solubility of the active ingredient increases at the basic side, the pH of the solution is raised by adding the alkaline agent in an amount more than equivalent to the acidic agent. In either case, the pH near the acidic agent immediately after the dissolution is low, while the pH near an alkaline agent is high." See col. 4, line 58 - col. 6, line 4. Thus, the alkaline and/or acidic agents of Robinson et al. will act not only as effervescent agents, but

also as pH adjusting agents. Robinson et al. teach that the amount of alkaline agent is usually selected from the range of from about 3% to about 70%, preferably from about 10% to 70% by weight based on the effervescent granule. See col. 5, lines 7-15. The amount of the effervescent granules in the tablets of Robinson et al. ranges from about 2 to about 90% by weight of the final tablet composition. See col. 8, lines 26-34. Robinson et al. teach that once the tablet is placed in the patient's mouth, it will completely disintegrate. See col. 8, lines 7-12. While teaching the claimed range, the Robinson reference does not explicitly teach that the amount of the effervescent couple should be greater than the amount necessary for tablet disintegration as required by the instant claims. However, the reference teaches that the amount of the effervescent agents as well as the ratio of acidic agent to alkaline agent can be selected in order to achieve the desired rate of effervescence, "substantially complete" disintegration of the tablet and, thus, a "positive organoleptic sensation to a patient". See col. 6, lines 1-37; col. 7, lines 24-34; col. 8, lines 2-13. Thus, the determination of optimal or workable amount of the effervescent agents by routine experimentation in order to achieve the aforementioned desired effect(s) is obvious absent showing of criticality of the claimed amount. One having ordinary skill in the art at the time the claimed invention was made would have been motivated to employ effervescent agents of Robinson et al. in the amount greater than the amount necessary for the disintegration of the tablet to insure "substantially complete" disintegration of the tablet and, as the result, a "positive organoleptic sensation to a patient".

9. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. as applied to claim 22 above, and further in view of Norling et al. (US 5,958,458).

Robinson et al. applied as above. While broadly teaching analgesics, Robinson et al. do not explicitly teach fentanyl of the instant claim. However, Norling et al. teach that fentanyl, among other analgesics, can be used in effervescent tablets including those of oral and buccal administration. See col. 6, lines 23-24; col. 12, lines 11-18; col. 13, lines 30-31; col. 36, Example 13. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the effervescent formulations of Robinson et al. such that to employ fentanyl. One having ordinary skill in the art would have been motivated to do this to obtain effervescent analgesic formulations as suggested by Norling et al.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,053,396 – discloses effervescent therapeutic formulations which may contain prochlorperazine.

11. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Marina Lamm
Patent Examiner AU 1616
7/30/03